



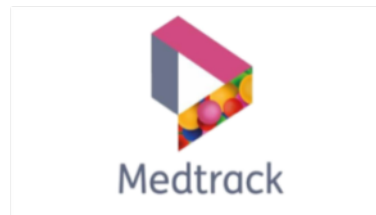
International Pricing Index

What Will be the Impact on Patients,
Outcomes, and Innovation?

June 5, 2019 - BIO

Duane Schulthess
Managing Director

This study was made possible with the support of



What is the IPI? HHS says the following...

- Medicare Part B drug cost is 1.8 times higher when compared to an international average of countries
- Medicare Part B drugs will be reimbursed based on their average cost in a basket of other countries, plus a mark-up (i.e. 1.26 times the average basket price in the initial HHS case study)
- Would initially focus on Part B drugs that encompass a high percentage of utilization and spending
- HHS will test this model under section 1115A of the Social Security Act – i.e. does not require congressional approval
- The model would operate for five years, from Spring 2020 to Spring 2025, starting in 50% of the Medicare Part B market
- Model will only impact R&D by 1%
- The pharmaceutical industry will be pressured to fairly allocate the burden of funding innovation across wealthy countries (i.e. raise prices in Europe, Japan)

Implementation Schedule

The potential phase-in would use the following blend of ASP and Target Price:

Year	Percentage of ASP and Target Price
Year 1	80 percent ASP and 20 percent Target Price
Year 2	60 percent ASP and 40 percent Target Price
Year 3	40 percent ASP and 60 percent Target Price
Year 4	20 percent ASP and 80 percent Target Price
Year 5	100 percent Target Price

- ASP is the “Average Sale Price” of the HCPCS class of drugs, Target Price is the average of International prices
- The model would move over 5 years to the full IPI target price

What Countries Were Benchmarked?

“The HHS analysis compared United States drug acquisition costs for a set of Medicare Part B physician-administered drugs to acquisition costs in 16 other developed economies Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden, and the United Kingdom(UK).”

The Situation in Europe – An Appropriate Benchmark?

The \$2m drug reveals medical research as a casino culture

Kenan Malik



Panic in Greek pharmacies as hundreds of medicines run short

Pharmaceutical companies accused of cutting supplies because of low profits and unpaid bills

06/06/2019



Fury as NHS rejects cystic fibrosis drug price offer

July 5, 2018

IPI By The Numbers - Methodology

- We used HHS' own IPI model to calculate the balance sheet impact of companies with products under Medicare Part B's revised pricing
- We take all financial corporate data from FY 2017
- Financials are taken from audited corporate annual reports and Medtrack by Informa
- Our analysis is limited to those medications where the price is above the calculated IPI 1.26 (126%) threshold (i.e. 20 products)
- We run three scenarios; the impact of the 50% Medicare IPI implementation at year 5, a 100% Medicare IPI implementation at year 5, and a Medicare IPI scenario that impacts all US pricing

Table 2. Comparisons of Price per Gram, U.S. and International Ex-Manufacturer Prices, Q1 2018.

Product	U.S. Price per Gram	U.S. Price Divided by Average International Price (U.S. = 1)	Country with Lowest Price	Country with Median Price	Country with Highest Price
Alimta (pemetrexed sodium)	\$4,690	2.0	39.7 (Canada)	1.8 (Japan)	1.3 (Austria)
Aranesp (darboepoetin alfa)	\$3,517,653	2.1	3.4 (Portugal)	2.4 (France)	1.3 (Belgium)
Avastin (bevacizumab)	\$6,504	2.0	2.4 (France)	2.2 (Japan)	1.5 (Belgium)
Cimzia (certolizumab pegol)	\$8,197	3.0	4.2 (France)	3.3 (Sweden)	2.2 (Germany)
Eligard/ Lupron (leuprolide acetate)	\$37,814	1.3	5.8 (Greece)	1.4 (Sweden)	0.95 (Japan)
Eylea (afibercept)	\$775,994	1.7	3.1 (Belgium)	1.6 (UK)	1.4 (Canada)
Gammagard (IVIG)	\$68	0.95	1.8 (Japan)	1.0 (France)	0.69 (Spain)
Gamunex-c/ Gammaked (IVIG)	\$67	1.1	1.8 (Sweden)	1.1 (Italy)	1.0 (Finland)
Herceptin (trastuzumab)	\$7,688	2.2	2.7 (Japan)	2.4 (Portugal)	1.5 (Germany)
Kadcyla (ado-trastuzumab emtansine)	\$26,249	1.3	1.6 (Canada)	1.2 (France)	1.0 (Spain)
Keytruda (pembrolizumab)	\$40,036	1.2	1.5 (Slovakia)	1.3 (UK)	0.91 (Spain)
Lucentis (ranibizumab)	\$3,270,469	5.4	9.8 (Greece)	6.9 (France)	1.4 (Japan)
Neulasta (pegfilgrastim)	\$588,937	3.2	4.7 (Portugal)	3.3 (France)	1.8 (Canada)
Opdivo (nivolumab)	\$22,856	1.4	1.9 (Germany)	1.5 (Sweden)	0.86 (Japan)
Orencia (abatacept)	\$4,381	2.3	3.2 (Slovakia)	2.5 (France)	1.6 (Germany)
Privigen (IVIG)	\$65	1.2	1.8 (Sweden)	1.3 (Belgium)	0.91 (Finland)
Prolia/Xgeva (denosumab)	\$15,575	4.6	5.9 (France)	4.8 (Japan)	3.4 (Canada)
Remicade (infliximab)	\$7,108	1.2	1.9 (Slovakia)	1.2 (Japan)	0.84 (Sweden)
Rituxan (rituximab)	\$6,597	2.7	4.3 (UK)	2.8 (Spain)	2.1 (Japan)
Sandostatin LAR (octreotide acetate)	\$111,548	2.7	6.1 (Spain)	3.1 (UK)	1.5 (Germany)
Soliris (eculizumab)	\$16,720	0.99	1.3 (UK)	1.0 (Italy)	0.86 (Germany)
Treanda (bendamustine)	\$24,138	6.9	34.2 (Sweden)	10.8 (France)	2.5 (Canada)
Tysabri (natalizumab)	\$18,674	2.9	4.1 (UK)	2.8 (France)	2.1 (Canada)
Velcade (bortezomib)	\$359,040	1.1	5.9 (Czech Republic)	1.0 (Italy)	0.82 (Germany)
Xolair (omalizumab)	\$6,128	2.2	2.9 (UK)	2.2 (Italy)	1.8 (Canada)
Yervoy (ipilimumab)	\$121,862	1.5	1.7 (Japan)	1.6 (Germany)	1.2 (Belgium)
Zaltrap (ziv-aflibercept)	\$7,413	1.7	2.1 (France)	1.6 (Italy)	1.3 (Japan)
All Products Total	N=27	1.8			

Source: IQVIA MIDAS. Analysis based on data released August 17, 2018.

IPI By The Numbers

50% Medicare Coverage – 100% Target Price

\$USD Millions

Company	Number of Therapies	2016 50% Medicare B Total Sales	Total New Revenue (Multiple 1.26)	Total Change in Revenue (\$US Mil)	Current R&D Budget (\$US Mil)	Potential R&D Impact	20% R&D Impact
Company A	3	1,376	506	-869	3,737	-23%	-5%
Company B	6	2,482	1,210	-1,272	10,529	-12%	-2%
Company C	1	132	24	-107	1,213	-9%	-2%
Company D	1	118	49	-68	1,057	-6%	-1%
Company E	1	1,104	818	-286	5,200	-5%	-1%
Company F	3	1,021	809	-212	4,894	-4%	-1%
Company G	1	153	66	-86	2,250	-4%	-1%
Company H	1	256	161	-95	5,357	-2%	0%
Company I	1	206	96	-110	8,510	-1%	0%
Company J	1	145	140	-4	10,329	0%	0%
Company K	1	3	2	-1	5,894	0%	0%
TOTAL	20	6,993	3,882	-3,110	58,970	-5.3%	-1%

IPI By The Numbers

100% Medicare Coverage – 100% Target Price
\$USD Millions

Company	Number of Therapies	2016 100% Medicare B Total Sales	Total New Revenue (Multiple 1.26)	Total Change in Revenue (\$US Mil)	Current R&D Budget (\$US Mil)	Potential R&D Impact	20% R&D Impact
Company A	3	2,751	1,013	-1,738	3,737	-47%	-9%
Company B	6	4,964	2,421	-2,543	10,529	-24%	-5%
Company C	1	263	48	-215	1,213	-18%	-4%
Company D	1	235	99	-136	1,057	-13%	-3%
Company E	1	2,208	1,637	-571	5,200	-11%	-2%
Company F	3	2,042	1,617	-425	4,894	-9%	-2%
Company G	1	305	133	-172	2,250	-8%	-2%
Company H	1	511	322	-189	5,357	-4%	-1%
Company I	1	411	192	-219	8,510	-3%	-1%
Company J	1	289	280	-9	10,329	0%	0%
Company K	1	6	4	-2	5,894	0%	0%
TOTAL	20	13,985	7,765	-6,220	58,970	-10.5%	-2%

But... What About the Non - Medicare Part B Market?

- Medicare Part B is less than half of product revenue
- HHS assumes these price ceilings will be contained to Medicare Part B



IPI By The Numbers

Impact on Total Product Sales – 100% Target Price

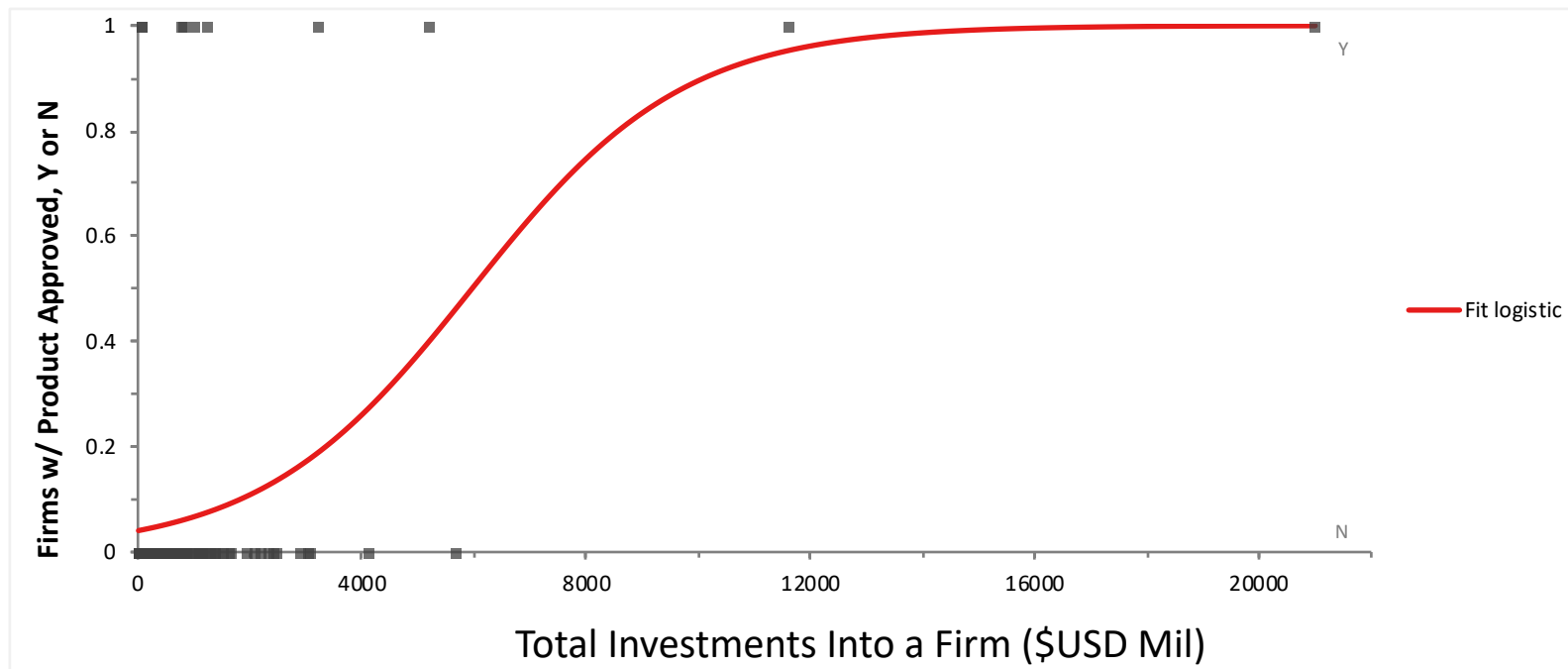
\$USD Millions

Company	Number of Therapies	Total 2017 US Sales IPI Impacted Products	Total New Revenue (Multiple 1.26)	Total Change in Revenue (\$US Mil)	Current R&D Budget (\$US Mil)	Potential R&D Impact	20% R&D Impact
Company A	3	6,308	2,498	-3,810	3,737	-102%	-20%
Company B	6	13,426	7,063	-6,362	10,529	-60%	-12%
Company D	1	918	386	-532	1,057	-50%	-10%
Company C	1	642	117	-525	1,213	-43%	-9%
Company G	1	1,114	484	-630	2,250	-28%	-6%
Company F	3	5,714	4,488	-1,226	4,894	-25%	-5%
Company E	1	4,080	3,024	-1,056	5,200	-20%	-4%
Company H	1	1,034	651	-383	5,357	-7%	-1%
Company I	1	832	388	-444	8,510	-5%	-1%
Company J	1	726	704	-22	10,329	0%	0%
Company K	1	10	7	-3	5,894	0%	0%
TOTAL	20	34,804	19,811	-14,993	58,970	-25.4%	-5%

How does reducing between \$6.2 - \$15 bil a year in revenue impact the investment ecosystem?

- We extracted a database of all publically disclosed biotech deals for a period of 5 years from January 1, 2014, to April 30, 2019, in California, Massachusetts, and North Carolina.
- We limited our search to companies that had made 'deals' with the 11 companies in our IPI research = 118 biotech companies in our final cohort.
- Of the 118 companies, 10 successfully brought a product to market with total investments from all sources (Acquisition, Partnership, Private Equity, Private Placement, Public Offering, Venture Financing) equaling \$45 Billion
- Our 11 companies impacted by the IPI invested \$39 bil of the \$45 bil (80%) of the total invested in the 10 companies that brought a product to market.

The Total Amount Invested in These 10 Companies Predicts the Probability of Success Bringing a Product to Market ($p=.0002$)



Logistic Regression Allows Us To Predict The Probability Of A Successful Market Entry For Any Given Total Investment

Y is Sum Product
Using Constant and slope of Grand Total

$$Y^* = \ln(p/1-p)$$

Probability of Success with Given
Investment (exp)

$$p = \exp(y^*) / (\exp(y^*) + 1)$$

Reducing Revenue For Ecosystem via IPI Impacts Investments & Radically Impacts the Probability of Successful Market Entry

Oncology Product	Current	50% Medicare (-\$15.5 bil)	100% Medicare (-\$31.1 Bil)
Total Investment \$US Mil	21,000	13,747	6,490
Probability of Success	100%	98%	57%

Hematology Product	Current	50% Medicare (-\$15.5 bil)	100% Medicare (-\$31.1 Bil)
Total Investment \$US Mil	11,600	7,594	3,585
Probability of Success	95%	70%	22%

CNS Product	Current	50% Medicare (-\$15.5 bil)	100% Medicare (-\$31.1 Bil)
Total Investment \$US Mil	5,194	3,400	1,605
Probability of Success	40%	20%	9%

Home Market Effect (Krugman 1980)

Why The US Dominates Global Biotech

The More We Die, The More We Sell?
A Simple Test of the Home-Market Effect*

Arnaud Costinot
MIT, CEPR, and NBER

Dave Donaldson
MIT, CEPR, and NBER

Margaret Kyle
Mines ParisTech and CEPR

Heidi Williams
MIT and NBER

October 2018

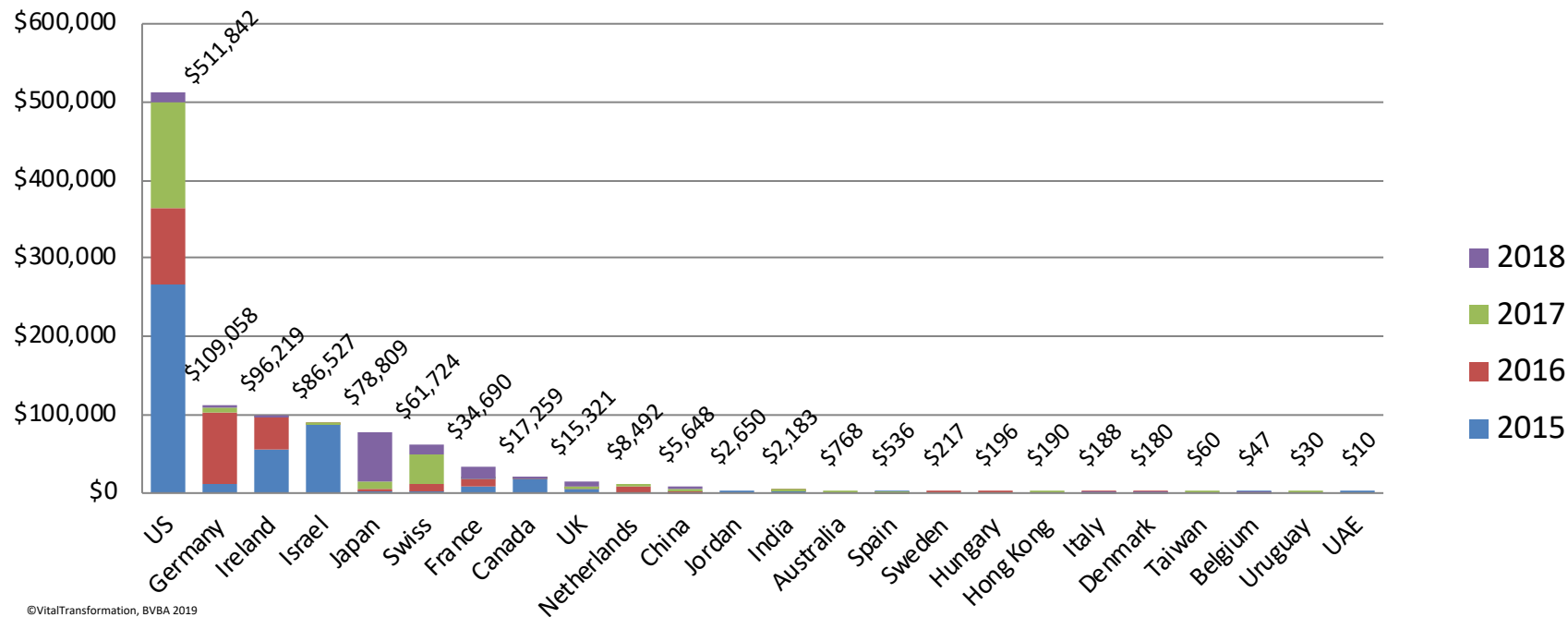
“Countries with larger demand for some products at home tend to have larger sales of the same products abroad. . . we develop a test of the home-market effect using detailed drug sales data from the global pharmaceutical industry.”

“Evidence for the weak home-market effect remains firm. . . it seems likely that the strong home-market effect is at work in the pharmaceutical sector”

BIOTECH M&A BY BUYING COUNTRY

2015 - 2018

\$US Millions



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<https://www.thepharmaletter.com/article/an-all-time-record-year-for-pharma-biotech-m-a>
<https://www.thepharmaletter.com/article/volume-and-value-of-pharma-biotech-m-a-slowed-down-in-2016>
<https://www.thepharmaletter.com/article/pharmaceutical-m-a-deals-in-2017>
<https://www.thepharmaletter.com/article/pharmaceutical-m-a-deals-in-2018>

Conclusions on IPI

- Is product based, ignoring the cumulative impact on companies that have multiple products in Medicare Part B
- Will negatively reduce revenues of innovative companies at a rate higher than 1% of R&D
- Penalizes innovation, targets companies with the most advanced, newest products in the market for what are often the most challenging diseases
- Will skew R&D away from Medicare Part B physician administered drugs
- Assumes companies will be able to raise prices in Europe; this is highly unlikely, and could lead to compulsory licenses against US products given the current EU political climate
- Assumes that Medicare Part B prices will not erode overall market pricing, this is wrong.
- Will radically reduce the amount of liquidity available for investments into new products/mergers/partnerships etc., negatively impacting market entry of new medicines
- Ignores the reality that the US is currently buying and 'owning' 70% of mature biotech and late stage value creation. Yes, the US pays more, but gets a lot more in return too.



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